

### **REMARKS**

Claims 1 and 5-11 constitute the pending claims in the present application. Among them, Claims 7 and 10 are directed to non-elected species, and are withdrawn from further consideration.

Applicant notes that the sIDS filed on 8/20/07 has been considered by the Examiner.

Applicant also notes with appreciation that the Examiner has withdrawn the rejections under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 103(a) in view of Applicant's claim amendments and arguments presented in the August 20, 2007 response.

Applicant respectfully requests reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

#### **Claim Rejections under 35 U.S.C. § 102(e)**

Claims 1, 5, 6, 8, 9, and 11 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by International Patent Application Publication WO 03/097011 A1 ("Barth"). The Office Action alleges that Barth "discloses a method of treating OSAS or obstructive sleep apnea (OSA), which is caused by a complete and/or *partial obstruction of the patient's airway* (a.k.a. obstructive hypopnea) (page 8, lines 9-14) by administering a therapeutically effective amount of at least one proton pump inhibitor ..." Therefore, the Office Action argues that Barth teaches treating partial upper airway obstruction (obstructive hypopnea) by using proton pump inhibitors.

Although Applicant still disagrees with the Examiner's read of Barth, Applicant / Inventor Warren Stern hereby provides a Rule 131 Declaration to remove Barth as a prior art reference under 35 U.S.C. § 102(e), thus overcoming the rejection.

Applicant notes that Barth is a PCT publication filed on May 16, 2003, claiming the benefit of the filing dates of U.S. Provisional Application Nos. 60/380,855, filed on May 17, 2002; 60/404,154, filed on August 19, 2002; and 60/449,838, filed on February 27, 2003. Upon reviewing the three U.S. priority documents, the quoted passage (from the Barth PCT application) first appeared in U.S. Provisional Application No. 60/404,154, filed on August 19, 2002, but not in U.S. Provisional Application No. 60/380,855, filed on May 17, 2002. In fact, U.S. Provisional Application No. 60/380,855, filed on May 17, 2002 does not refer to "snoring" or "partial airway

obstruction” even once. Therefore, Barth is at best entitled to the filing date of August 19, 2002 with respect to “snoring” or “partial airway obstruction.” In other words, the Barth PCT application is at best entitled to an earliest effective prior art reference date of August 19, 2002, and certainly, under no circumstances, the earliest effective date can be earlier than May 17, 2002.

According to the Rule 131 Declaration, Applicant *conceived* the inventive concept pertaining to the presently claimed invention, and *actually reduced it to practice* (see, for example, Example 1) prior to May 17, 2002, the earliest claimed priority and the earliest possible effective date of the Barth PCT application.

Specifically, **Exhibit A** is a copy of an Agreement entered between inventor Warren Stern and SohnStearns, LLC, on a date (redacted) before May 17, 2002. The Agreement relates to the formation of a new company “Newco,” for the purpose of developing intellectual property, obtaining patents, and commercializing a pharmaceutical for the treatment of snoring, sleep apnea and related disorders (see paragraphs 1 and 2 of the Agreement). Under the Agreement, the inventor’s sole contribution to the Newco appears to be providing Newco with intellectual property related to snoring (paragraph 4 of the Agreement), and contributing to Newco a protocol for performing clinical trials for the snoring related pharmaceutical (paragraph 7 of the Agreement). **This shows that the inventor was in possession of the invention and a clinical trial protocol as of the date of the Agreement, which is prior to May 17, 2002.**

**Exhibit B** is a Confidentiality Agreement entered between Doug Bell, M.D., then a clinical instructor at Harvard Medical School, and Steve Sohn, M.D., a member of SohnStearns, LLC, on a dated (redacted) before May 17, 2002. Pursuant to the Confidentiality Agreement, Dr. Bell will receive information related my invention “concerning a new pharmaceutical treatment of snoring, insomnia and related sleep disorders,” for the purpose of conducting clinical trials in a group of snoring patients in order to further verify the claimed invention. **This also shows that the inventor was in possession of the invention and a clinical trial protocol as of the date of the Confidentiality Agreement, which is prior to May 17, 2002.**

**Exhibit C** is one of eight Data Extraction Forms used in the study conducted under the Confidentiality Agreement shown in **Exhibit B**, and subsequently described in Example 2 of the

above-referenced application. The Data Extraction Form indicates that the start date for this patient was prior to May 17, 2002, and the end date for this patient was prior to August 19, 2002 (the filing date of the Barth U.S. Provisional Application 60/404,154). **This further shows that the inventor was in possession of the invention prior to May 17, 2002, or at least prior to August 19, 2002.**

Each of these Exhibits alone disqualifies the Barth PCT Application as a prior art reference under 35 U.S.C. § 102(e) against the instant application.

Furthermore, Applicant has also *constructively reduced the inventive concept to practice*, by filing a U.S. Provisional Patent Application 60/419,072 on October 16, 2002, and Applicant has been diligent from just prior to August 19, 2002 till October 16, 2002, when the provisional application 60/419,072 was filed. *See*, for example, **Exhibits B and C** (and maybe to a lesser extent, **Exhibit A**). This constitute a second, independent ground to antedate the Barth PCT Application as prior art under 35 U.S.C. § 102(e).

Finally, Applicant submits that the Rule 131 Declaration is properly submitted with this response, since it is necessary to overcome the only remaining novelty rejection. Applicant further submits that the Rule 131 Declaration was not earlier presented, because Applicant believed (and still believes) that the arguments and claim amendments filed in the previous response would be sufficient to overcome the indefiniteness, anticipation, and obviousness rejections. Applicant submits that Applicant is entitled to present arguments in the record to support patentability and to overcome prior art rejection, without having to resort to antedating the cited reference.

While Applicant still believes that the arguments and claim amendments filed in the previous response should be sufficient to overcome the novelty rejection based on the Barth PCT Application, solely to expedite prosecution, Applicant has submitted the instant Rule 131 Declaration. Applicant does not acquiescing in the reasoning of the instant Office Action in maintaining the novelty rejection based on Barth.

In summary, the Barth PCT publication is disqualified as a prior art reference under 35 U.S.C. § 102(e). Reconsideration and withdrawal of the rejection based on Barth are respectfully requested.

**CONCLUSION**

In view of the above amendments, Applicant believes the pending application is in condition for allowance. Applicant believes no fee is due with this response. However, if any fee is due, please charge our Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under Order No. **SOHN-P01-001**.

Dated: June 11, 2008

Respectfully submitted,

By  \_\_\_\_\_

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